IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	**:**	**DATE FILED:**
v.	**:**	**CRIMINAL NUMBER**
SCHERING SALES CORPORATION (A SUBSIDIARY OF SCHERING-PLOUGH CORPORATION)	**:**	**VIOLATION: 42 U.S.C. § 1320a-7b (illegal remuneration - 1 count)**

I N F O R M A T I O N

COUNT ONE

THE UNITED STATES ATTORNEY CHARGES THAT:

At all times material to this Information:

THE DEFENDANT CORPORATION

1. Schering Sales Corporation ("Schering Sales") was a Delaware corporation with its principal place of business in Kenilworth, New Jersey. Schering Sales was a wholly owned subsidiary of Schering Corporation, which in turn was a wholly owned subsidiary of Schering-Plough Corporation. Schering-Plough Corporation and its subsidiaries, including Schering Sales, will be referred to in this Information collectively as "Schering."

2. Schering developed, manufactured and marketed drugs, including Claritin, a prescription drug used for the treatment of allergies. The purpose of Schering Sales was to market and sell drugs manufactured by Schering-Plough Corporation. Schering Sales employed a sales force to do this. Among the types of businesses to which Schering Sales endeavored to sell Schering drugs were health maintenance organizations ("HMOs").

HEALTH MAINTENANCE ORGANIZATIONS

3. An HMO is a type of managed care health insurance plan that arranges for and provides health care benefits to its members in exchange for the members' payments of premiums. One way in which HMOs manage care is by providing members with limited options, including limited choices of physicians and limited coverage of drugs. A member can obtain treatment outside the limited options available at the member's own expense.

4. HMOs maintain "formularies" of drugs. A formulary is a list of approved drugs that an HMO recommends physicians prescribe for its health plan members. HMOs promote their formularies by advising their participating physicians and members of the approved drugs included on the formularies. When a member's physician prescribes a drug on the HMO formulary, the member can obtain the drug at a pharmacy for payment of a small amount, called a co-pay; the HMO pays the balance of the cost. If a member obtains a drug that is not on the formulary, the member pays the full retail price to the pharmacy and the HMO pays no reimbursement.

CLARITIN VS. ALLEGRA

5. Claritin was Schering's best-selling and most profitable product.

6. Claritin's main competitor was Allegra, a substantially less expensive and therapeutically equivalent drug.

7. From in or about March 1993 through 2002, Schering Sales marketed and sold Claritin.

THE SCHERING-HMO RELATIONSHIP

8. It was the practice in the industry for drug manufacturers to pay rebates to HMOs when HMO members used the manufacturers' drugs included on the HMOs' formularies. These rebates were reflected in reimbursement contracts between the drug manufacturers and HMOs.

9. In 1997 Schering and a particular HMO, known to the United States Attorney ("the HMO"), executed reimbursement contracts to govern the prices available to the HMO on all Schering drugs on the HMO's formulary. Under these contracts, Schering paid the HMO quarterly rebates for each Schering drug included on the HMO's formulary, based upon the quantities of each drug used by the HMO's members in that quarter.

10. Schering's reimbursement contracts required the HMO to provide quarterly data about the use of Schering drugs by the HMO's members before Schering paid the HMO its rebate. The quarterly data provided by the HMO included total amount of each Schering drug used, total rebate claimed for each drug, and market share information for use of both Schering and competitor drugs for each of the HMO's regional health plans.

11. The HMO had a National Pharmacy and Therapeutics Committee ("P & T committee") that decided which drugs to include and exclude from its formulary. The P & T committee included pharmacists, medical directors and others from the HMO's regional plans. The committee met regularly to evaluate drugs for safety, efficacy, therapeutic alternatives and cost.

CLARITIN REIMBURSEMENT BY MEDICAID

12. The Medicaid Program is a health care insurance program for the poor, funded in part by the federal government and in part by each state.

13. All drug manufacturers that want to participate in the Medicaid drug program, and thereby have their drugs covered for use by Medicaid beneficiaries, are subject to the requirements of the Medicaid Drug Rebate Statute.

14. The Medicaid Drug Rebate Statute requires manufacturers participating in the Medicaid program to provide Medicaid with the best price they offer to any commercial customer. Best price is defined by law as: "The lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity or governmental entity."

15. The Medicaid Drug Rebate Program is administered by the United States Department of Health and Human Services ("HHS"), which requires that all participating drug manufacturers enter into a Medicaid rebate agreement.

16. On or about February 28, 1991, Schering entered into a Medicaid Rebate Agreement with HHS that allowed Schering drugs, including Claritin, to be covered by Medicaid.

17. Under this agreement, Schering agreed to file quarterly reports with HHS certifying the "best price" available for each of its drugs, and to pay the Medicaid program the resulting rebates for all Schering drugs used by Medicaid beneficiaries in that quarter.

18. Schering Sales was aware of the best price reporting requirements and reported quarterly pricing information to Medicaid.

SCHERING-HMO DISPUTE OVER THE PRICE OF CLARITIN

19. In 1997 and 1998, the HMO repeatedly demanded a reduction in the high price of Claritin. Schering Sales refused to reduce the price of Claritin, in part because it knew that doing so would lower the Medicaid "best price" of Claritin and would require Schering to pay higher rebates to Medicaid.

20. In September 1998, as a result of Schering Sales' refusal to lower the price of Claritin, the HMO's National P & T committee voted to remove Claritin from the HMO formulary. Allegra, a significantly cheaper and therapeutically equivalent drug, remained on the HMO's formulary.

21. In or about September 1998, Schering Sales learned that the HMO planned to remove Claritin from its formulary because it was too expensive. Schering Sales knew that it cost the HMO several million dollars extra per year to purchase Claritin rather than Allegra. Schering Sales therefore developed a plan to make up the difference between the price of Claritin and Allegra by offering the HMO added value, in lieu of a direct price reduction, to offset the higher price of Claritin. The "added value" offers included reduced prices on other goods and services that would lower the HMO's total costs, without appearing to lower the cost of Claritin.

22. Between September 1998 and February 1999, Schering Sales offered a number of proposals to the HMO that provided other financial value to the HMO to avoid reducing the price of Claritin. The HMO rejected all of these offers.

23. Finally, to induce the HMO to keep Claritin on the formulary at a high price, on or about February 24, 1999, Schering Sales offered a $10 million per year package of added value that effectively and indirectly reduced the HMO's cost for Claritin for a three-year period. The HMO accepted this offer and retained Claritin on its formulary.

24. As part of this package of value, Schering Sales offered to pay the HMO an annual fee of 2% of the annual gross sales of Schering drugs to the HMO, which Schering Sales calculated as worth approximately $2.4 million per year.

25. Schering Sales disguised the true nature of the 2% fee by calling it a "data fee," to give the appearance that the payment was a fair-market-value transaction rather than a hidden inducement to the HMO to keep Claritin on its formulary. As part of its concealment of the true nature of the 2% fee, Schering Sales agreed to pay the HMO a data fee to purchase an annual cumulative report from the HMO. In fact, the annual report was to contain the identical information that the HMO was already providing to Schering Sales in its quarterly reports, as required under its pre-existing reimbursement contracts. The annual report provided no additional information.

26. In February 2000, Schering Sales received the HMO's first annual cumulative report containing the exact same information the HMO had already provided to Schering Sales in each of the three previous quarters.

27. Schering Sales never used the annual report, which consisted of electronic data in a format that Schering Sales had difficulty accessing.

28. On or about August 3, 2000, Schering Sales caused Schering to pay the HMO $1,831,966.99 for the report (2% of total dollar value of Schering drugs used by the HMO's members for the applicable period).

THE CHARGES

29. Between in or about January 1999 and in or about August 2000, in the Eastern District of Pennsylvania and elsewhere, defendant

SCHERING SALES CORPORATION

knowingly and willfully offered and paid, and willfully caused to be paid, remuneration, that is, a kickback in the sum of $1,831,966.99, disguised as a data fee, directly and indirectly, overtly and covertly, in cash and in kind, to the HMO to induce the HMO to purchase, order, arrange for and recommend to its members and their physicians that those physicians prescribe and their members purchase and order the drug Claritin, payment for which drug may be made in whole and in part under federal health care programs.

All in violation of Title 42, United States Code, Section 1320a-7b(b)(2)(B) and Title 18, United States Code, Section 2.

PATRICK L. MEEHAN
United States Attorney